

IN THE ARBITRATION UNDER CHAPTER ELEVEN  
OF THE NORTH AMERICAN FREE TRADE AGREEMENT  
AND THE UNCITRAL ARBITRATION RULES (1976)  
BETWEEN

APOTEX INC.,

*Claimant/Investor,*

*-and-*

UNITED STATES OF AMERICA,

*Respondent/Party.*

**REPLY ON OBJECTIONS TO JURISDICTION OF  
RESPONDENT UNITED STATES OF AMERICA**

Jeffrey D. Kovar  
*Assistant Legal Adviser*  
Lisa J. Grosh  
*Deputy Assistant Legal Adviser*  
Jeremy K. Sharpe  
*Chief, Investment Arbitration*  
Neale H. Bergman  
David M. Bigge  
Alicia L. Cate  
Patrick W. Pearsall  
*Attorney-Advisers*  
*Office of International Claims*  
*and Investment Disputes*  
UNITED STATES DEPARTMENT OF STATE  
Washington, D.C. 20520

October 17, 2011

## TABLE OF CONTENTS

PRELIMINARY STATEMENT .....	1
ARGUMENT .....	5
I.    Apotex Is Not An Investor With An Investment In The United States, And Thus Lacks Standing Under Article 1116 Of NAFTA’s Investment Chapter .....	5
A.    Apotex’s Applications For Permission To Export Generic Drugs Are Not “Investments” In The United States .....	6
B.    Apotex Has Not Made “Investments” In The United States Merely Because It Purchased Goods In The United States For Export, Designated A U.S. Agent And Distributor, And Incurred Litigation Expenses In The United States .....	14
II.   The Regulatory And Judicial Measures Underlying Apotex’s Pravastatin Claims Fall Outside The Tribunal’s Jurisdiction.....	18
A.    Apotex’s Challenge To An FDA Measure Older Than Three Years Is Barred By NAFTA’s Three-Year Limitations Period.....	20
B.    Apotex Acknowledges That It Cannot Challenge Non-Final Judicial Acts, But Erroneously Claims That It Would Have Been “Obviously Futile” To Seek Finality In U.S. Courts.....	25
1.    Apotex’s Excuse For Failing To Exhaust Available Judicial Remedies Is Insufficient.....	26
2.    Apotex’s Argument That Its Appeal Was Moot Is Incorrect .....	28
RELIEF SOUGHT .....	34

**REPLY ON OBJECTIONS TO JURISDICTION OF  
RESPONDENT UNITED STATES OF AMERICA**

1. Pursuant to Article 21 of the UNCITRAL Arbitration Rules (1976), and in accordance with the Tribunal's Procedural Order No. 1 of December 16, 2010, the United States of America respectfully submits its Reply on Objections to Jurisdiction.

**PRELIMINARY STATEMENT**

2. Apotex Inc. (Apotex) is a Canadian manufacturer of generic drugs. The company has extensive facilities in Canada for developing, testing, producing, and labeling its drugs. By its own admission, "Apotex does not reside or have a place of business in the United States." Instead, Apotex exports its drugs from Canada to more than 115 countries around the world, including the United States, where they are sold by others.

3. Apotex alleges in this arbitration that it incurred substantial costs making abbreviated new drug applications (ANDAs) and complying with related regulatory standards in its testing, manufacturing, and labeling operations in Canada to allow export of its generic sertraline and pravastatin drugs to the United States. Apotex does not allege that the United States rejected its sertraline and pravastatin ANDAs. To the contrary, Apotex acknowledges that the U.S. government granted final approval of its ANDAs in 2006 and 2007, thereby allowing Apotex to export its drugs to the United States for sale by others. Nor does Apotex allege that it was the first applicant of "paragraph IV certifications" for generic sertraline or pravastatin drugs, making it eligible for 180 days of market exclusivity. Rather, Apotex challenged other companies' 180-day market exclusivity of generic sertraline and pravastatin drugs, and claims that Apotex's own generic drugs should have been available for sale in the United States just months earlier than

was permitted. Apotex believes that this NAFTA investment tribunal is the appropriate forum to address that complaint.

4. This Tribunal lacks jurisdiction to hear Apotex's claims, for three reasons. *First*, Apotex lacks standing to bring a claim under NAFTA Chapter Eleven. Apotex purports to be an "investor" that made "investments" in the territory of the United States, but it has produced no evidence to that effect, and its own pleadings affirmatively belie its conclusory statements.

5. Apotex asserts, without establishing, that an ANDA is an "investment" under Article 1139(g), because it constitutes "property" in the United States. Apotex's claims, however, are not related to its approved ANDAs. Apotex thus asserts that its *tentatively-approved* applications for revocable permission to export its generic products to the United States for sale by others constitute property in the United States. Whether tentatively or finally approved, however, ANDAs are not "property" for purposes of NAFTA Chapter Eleven.

6. Apotex further claims to have made an "investment" as defined in Article 1139(h), which includes "interests arising from the commitment of capital or other resources in the territory of a Party to economic activity in such territory[.]" Illustrative examples under Article 1139(h) include interests in a construction contract or a government concession. Apotex's only evidence of these alleged "interests" consists of statements that the company (1) purchased goods in the United States for export to Canada for purposes of manufacturing its products there; (2) designated an agent and distributor to sell its products in the United States; and (3) incurred expenses from filing lawsuits in U.S. courts concerning its drug applications.

7. These activities, on their face, are not "interests" arising from the commitment of capital or other resources in the United States, and thus are not "investments in the territory of the

United States” under NAFTA Chapter Eleven. Indeed, if a Canadian or Mexican exporter could transform itself into an “investor” with an “investment” in the United States simply by designating a U.S. agent and distributor, purchasing U.S. goods for export, and filing a lawsuit to further its cross-border trade, then presumably every such exporter could bring its trade-related disputes to investment arbitration under the NAFTA. NAFTA Chapter Eleven, however, expressly defines the “investors” and “investments” entitled to protection so as to prohibit such bootstrapping. On the terms of Apotex’s own submission, it is not an investor that has made investments under NAFTA Chapter Eleven, and thus its claims should be dismissed in their entirety.

8. *Second*, regardless of whether Apotex qualifies as an “investor” or its activities were “investments” under the NAFTA, the Tribunal cannot hear Apotex’s pravastatin claim challenging a final ruling of the U.S. Food and Drug Administration (FDA), as that claim is time-barred. Apotex acknowledges that, in accordance with NAFTA Article 1116(2), it cannot bring a claim if more than three years have elapsed from the date on which it first acquired, or should have acquired, knowledge of an alleged breach and resulting loss or damage. Apotex further acknowledges that the challenged FDA measure occurred more than three years before Apotex brought its NAFTA claim. Apotex contends, however, that bringing a court action against a regulatory measure somehow revives or tolls claims based on that measure. Apotex has cited no support for this assertion, and, in fact, NAFTA Chapter Eleven tribunals have specifically rejected such an argument. Were it otherwise, any claimant could evade NAFTA’s clear and rigid limitations period by seeking judicial review of a challenged measure within three years of filing a NAFTA claim. Apotex’s argument thus must be rejected, along with its challenge to the FDA measure.

9. *Third*—again assuming for the purpose of argument that Apotex could meet the threshold for protection under the NAFTA as an investor—the Tribunal cannot hear Apotex’s challenge to the U.S. courts’ adjudication of Apotex’s pravastatin claim, because Apotex failed to obtain the judicial finality that is required before bringing an international claim. Apotex concedes that a claimant challenging a court action under NAFTA Chapter Eleven must obtain a final decision of the highest court of the host State, unless further judicial recourse would have been “obviously futile.” Apotex further concedes that after the U.S. Court of Appeals for the D.C. Circuit denied *en banc* Apotex’s petition for rehearing its motion for a preliminary injunction, Apotex could have sought certiorari from the U.S. Supreme Court or resumed its claim in the district court for a decision on the merits. Apotex contends, however, that such action would have been pointless, as the 180-day market exclusivity for generic pravastatin granted to another company likely would have run in 67 days, before either court could have given Apotex the relief it sought.

10. Apotex’s excuse is both insufficient and erroneous. Apotex cannot challenge non-final judicial acts under NAFTA Chapter Eleven unless it demonstrates *obvious futility*, not the improbability of success. Under international law, the question of whether the failure to obtain judicial finality may be excused for “obvious futility” turns on the unavailability of relief by a higher judicial authority, not on measuring the likelihood that the higher judicial authority would have granted the desired relief.

11. As a factual matter, moreover, although the 180-day market exclusivity period had begun to run on the 10, 20, and 40 mg strengths of pravastatin, it had not begun to run on the 80 mg strength, and thus Apotex had ample time, at a minimum, to continue litigating its claim on the merits with respect to that strength. Apotex had two avenues to pursue further relief in U.S.

courts, but chose instead to dismiss its claims voluntarily. Apotex's pravastatin claim based on judicial acts, therefore, must be dismissed.

12. For these reasons, and those set forth below, the Tribunal should dismiss Apotex's claims in their entirety for lack of jurisdiction, and award costs to the United States.

## ARGUMENT

### **I. Apotex Is Not An Investor With An Investment In The United States, And Thus Lacks Standing Under Article 1116 Of NAFTA's Investment Chapter**

13. Apotex has brought a claim under NAFTA Article 1116<sup>1</sup> alleging that it is an "investor" with an "investment" in the United States as those terms are defined in Article 1139.<sup>2</sup> Article 1139 is "exclusive" rather than "illustrative," and is "neither broad nor open-textured."<sup>3</sup> Apotex has failed to carry its burden of establishing that it is an investor with an Article 1139-qualifying investment in the United States,<sup>4</sup> and thus all of its claims fall outside the Tribunal's jurisdiction.

---

<sup>1</sup> NAFTA Article 1116 addresses claims brought by an investor on its own behalf—as opposed to claims brought by an investor on behalf of an enterprise, which are addressed in Article 1117, and which are not at issue in this case. Article 1116(1) provides in relevant part: "An Investor of a Party may submit to arbitration under this Section a claim that another Party has breached an obligation under: (a) Section A ["Investment"] . . . and that the investor incurred loss or damage by reason of, or arising out of, that breach."

<sup>2</sup> Counter-Memorial of Claimant Apotex Inc. ¶ 33 (Aug. 1, 2011) ("Counter-Mem."); *see also* NAFTA art. 1139 (defining "investor of a Party" as "a national or an enterprise . . . that seeks to make, is making or has made an investment," and defining "investment" in sub-parts (a)–(h)).

<sup>3</sup> *Grand River Enterprises Six Nations, Ltd. v. United States*, NAFTA/UNCITRAL, Award ¶ 82 (Jan. 12, 2011) (In contrast to the "ICSID Convention or other regional and bilateral treaties . . . containing broad and sometimes open-textured definitions of investment . . . NAFTA's Article 1139 is neither broad nor open-textured," but "prescribes an exclusive list of elements or activities that constitute an investment for purposes of NAFTA") [R76].

<sup>4</sup> *See* UNCITRAL Arbitration Rules (1976), art. 24(1) ("Each party shall have the burden of proving the facts relied on to support [its] claim or defence.") [R84]; *see also* Memorial of Respondent United States on Objections to Jurisdiction ¶ 28, n.59 (May 16, 2011) ("Mem.") (citing additional authority); *Bayview Irrigation District v. Mexico*, ICSID Case No. ARB(AF)/05/01, Award on Jurisdiction ¶¶ 63, 122 (June 19, 2007) (finding that "Claimants have not demonstrated that their claims fall within the scope and coverage of NAFTA Chapter Eleven," and rejecting the argument that "Respondent bears the burden of demonstrating that the Tribunal should not hear the claim, and that in this context the Tribunal should assume that the facts alleged by the Claimants are true") [R69]; *Grand River Award* ¶ 122 ("[G]iven the relatively restricted definition of 'investment' under Article 1139, the Claimants must . . . establish an investment that falls within one or more of the categories established by that Article.") [R76].

14. Apotex concedes that it “does not reside or have a place of business in the United States[.]”<sup>5</sup> Apotex, moreover, does not claim to formulate, develop, test, manufacture, or label its generic drugs in the United States, as all of those activities occur in Canada.

15. Instead, Apotex identifies four business activities it claims to have conducted in the United States to facilitate its sertraline and pravastatin exports, and argues that, separately or together, those activities meet the NAFTA’s definition of “investment”: (1) Apotex’s “preparing and filing” of applications with FDA for permission to market its generic drugs in the United States for sale by others, and costs associated with seeking such approval; (2) Apotex’s purchase of inactive ingredients from U.S.-based suppliers for export to Canada; (3) Apotex’s designation of Apotex Corp. as its U.S. agent and distributor; and (4) Apotex’s retention of counsel for litigation in U.S. courts concerning its drug applications.<sup>6</sup> None of these activities are “investments” under NAFTA Article 1139, and therefore Apotex is not an “investor” with standing to bring a claim under NAFTA Chapter Eleven.

**A. Apotex’s Applications For Permission To Export Generic Drugs Are Not “Investments” In The United States**

16. Apotex claims that its ANDAs fall under Article 1139(g) and, as such, are “investments” under the NAFTA.<sup>7</sup> Article 1139(g) defines “investment” as including “real estate or other property, tangible or intangible, acquired in the expectation or used for the purpose of economic benefit or other business purposes.” Apotex has not established under Article 1139(g) that, on the date its claims arose, its ANDAs were property acquired or used. Instead, those ANDAs were *tentatively-approved* applications for revocable permission to export generic drugs to the

---

<sup>5</sup> Counter-Mem. ¶ 50 & n.56 (citing Witness Statement of Bernice Tao ¶¶ 14, 25 (Aug. 1, 2011) [C39]).

<sup>6</sup> Counter-Mem. ¶¶ 4, 36-63.

<sup>7</sup> *Id.* ¶ 36.



United States for sale by “others.”<sup>8</sup> As such, those applications do not constitute property qualifying for protection as “investments” under Article 1139(g).

17. Although Apotex’s sertraline and pravastatin ANDAs received final FDA approval in 2006<sup>9</sup> and 2007,<sup>10</sup> there is no dispute that Apotex’s ANDAs had only been tentatively approved on the date of the alleged NAFTA breaches.<sup>11</sup> FDA grants “tentative approval” to an ANDA when all scientific and procedural conditions for approval have been met, but FDA cannot finally approve an ANDA until various other barriers to approval no longer apply.<sup>12</sup> An application with a tentative approval will not become finally approved until FDA issues a final approval letter.<sup>13</sup> Final approval of a tentatively-approved ANDA, moreover, is not automatic, because FDA still “has an ongoing health and safety responsibility to perform.”<sup>14</sup>

---

<sup>8</sup> Notice of Arbitration related to sertraline claim ¶ 13 (Dec. 10, 2008) (“Sertraline NOA”); Notice of Arbitration related to pravastatin claim ¶ 13 (June 4, 2009) (“Pravastatin NOA”) (noting that its sertraline and pravastatin products would be “sold by others” in the United States).

<sup>9</sup> FDA tentatively approved Apotex’s sertraline ANDA in September 2006 and gave final approval in February 2007. See FDA Tentative Approval for Sertraline Hydrochloride Tablets (25, 50, and 100 mgs) (Sept. 27, 2006) [R96]; FDA Final Approval for Sertraline Hydrochloride Tablets (25, 50, and 100 mgs) (Feb. 6, 2007) [R97]. Apotex alleges that the sertraline-related NAFTA breaches occurred not later than October 2006, prior to final approval of its sertraline ANDA. Sertraline NOA ¶¶ 55-56.

<sup>10</sup> FDA tentatively approved Apotex’s pravastatin ANDA in September 2003 for the 10, 20, and 40 mg doses, and in October 2006 for the 80 mg dose. See FDA Tentative Approval for Pravastatin Sodium Tablets (10, 20, and 40 mgs) (Sept. 30, 2003) [R98]; FDA Tentative Approval for Pravastatin Sodium Tablets (10, 20, 40, and 80 mgs) (Apr. 25, 2006) [R99]; FDA gave final approval for Apotex’s pravastatin ANDA in October 2006 for the 10, 20, and 40 mg doses and in December 2007 for the 80 mg dose. See FDA Final Approval for Pravastatin Sodium Tablets (10, 20, and 40 mgs) and Tentative Approval for Pravastatin Sodium Tablets (80 mg) (Oct. 23, 2006) [R100]; FDA Final Approval for Pravastatin Sodium Tablets (80 mg) (Dec. 28, 2007) [R101]. Apotex alleges that the pravastatin-related NAFTA breaches occurred not later than August 2006, prior to final approval of any dose. Pravastatin NOA ¶ 31.

<sup>11</sup> See *id.*

<sup>12</sup> See 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA) [R3]; 21 C.F.R. § 314.107(b) [R89].

<sup>13</sup> See 21 C.F.R. § 314.107(b)(3)(v) [R89].

<sup>14</sup> *Ranbaxy Labs. Ltd. v. FDA*, 307 F. Supp. 2d 15, 19, 21 (D.D.C. 2004) [R114].

18. In Apotex's case, FDA informed the company that its tentatively-approved applications for sertraline and pravastatin were "subject to change on the basis of new information that may come to [FDA's] attention."<sup>15</sup> The same letters instructed Apotex to apply for final approval of its ANDAs, and stated that the tentative approval could be rescinded.<sup>16</sup> As part of the application process, Apotex received several notices of deficiency for both sertraline and pravastatin, including at least one notice following tentative approval.<sup>17</sup> These notices required Apotex to supplement its ANDAs with additional information before they could be finally approved and before permission could be granted to export its generic drugs to the United States for sale by others.<sup>18</sup>

19. There is no dispute that Apotex's ANDAs were at all times subject to extensive government regulation in order to provide for the safety of consumers in the U.S. market. Apotex itself highlights that the ANDA process requires significant government review and compliance with strict and detailed standards for virtually all aspects of the testing,

---

<sup>15</sup> FDA Tentative Approval for Sertraline Hydrochloride Tablets (25, 50, and 100 mgs) (Sept. 27, 2006) [R96]; *see also* FDA Tentative Approval for Pravastatin Sodium Tablets (10, 20, and 40 mgs) (Sept. 30, 2003) [R98]; FDA Tentative Approval for Pravastatin Sodium Tablets (10, 20, 40, and 80 mgs) (Apr. 25, 2006) [R99]; FDA Final Approval for Pravastatin Sodium Tablets (10, 20, and 40 mgs) and Tentative Approval for Pravastatin Sodium Tablets (80 mg) (Oct. 23, 2006) [R100]. Each letter states that FDA's decision is "subject to change on the basis of new information that may come to our attention."

<sup>16</sup> *Id.*

<sup>17</sup> *See* Pre-Tentative Approval FDA Deficiency Letter for Sertraline Tablets (25, 50, and 100 mgs) (Apr. 9, 2004) [R102]; Pre-Tentative Approval FDA Deficiency Letter for Sertraline Tablets (25, 50, and 100 mgs) (Nov. 26, 2004) [R103]; Pre-Tentative Approval FDA Deficiency Letter for Sertraline Tablets (25, 50, and 100 mgs) (Aug. 23, 2005) [R104]; Pre-Tentative Approval FDA Deficiency Letter for Sertraline Tablets (25, 50, and 100 mgs) (Aug. 7, 2006) [R105]; Post-Tentative Approval Letter for Sertraline Tablets (25, 50, and 100 mgs) from Apotex Inc. to FDA (Dec. 1, 2006) (noting a call from FDA on November 30, 2006 to Apotex Inc. requesting further information related to the application) [R106]; Pre-Tentative Approval FDA Deficiency Letter for Pravastatin Sodium Tablets (10, 20, and 40 mgs) (July 9, 2002) [R107]; Pre-Tentative Approval FDA Deficiency Letter for Pravastatin Sodium Tablets (10, 20, and 40 mgs) (Nov. 7, 2002) [R108]; Post-Tentative Approval FDA Deficiency Letter for Pravastatin Sodium Tablets (10, 20, 40, and 80 mgs) (Oct. 27, 2004) [R109].

<sup>18</sup> *Id.*

manufacturing, and labeling of the generic drug.<sup>19</sup> As such, the ANDA applicant continues to submit to an ongoing obligation to comply with the ANDA's requirements or it loses permission to sell its products.<sup>20</sup>

20. Even *finally approved* ANDAs can be revoked by FDA for numerous public health and policy reasons under U.S. law without giving rise to compensation.<sup>21</sup> The United States is not aware of any case in which a takings claim has been made for non-approval or revocation of an ANDA. Indeed, when FDA previously revoked one of Apotex's finally-approved ANDAs for a different generic drug, Apotex did not claim in U.S. court that it was entitled to compensation or that its ANDA constituted "property."<sup>22</sup> Apotex thus cannot now claim that an ANDA, whether tentatively approved or finally approved, is "property acquired" under the NAFTA.

21. Apotex argues, in three conclusory sentences, that its tentatively-approved ANDAs "unquestionably" are property for purposes of Article 1139(g) because they contain "confidential

---

<sup>19</sup> In its Counter-Memorial, Apotex identifies numerous FDA requirements it had to meet before its ANDAs could be approved:

In order to sell a product in the United States, an ANDA applicant also must meet FDA's so-called "Current Good Manufacturing Practice for Finished Pharmaceuticals," which impose strict requirements governing the testing, manufacturing and labeling of the ANDA products. . . .

An ANDA applicant further must meet specific requirements relating to the design, size, location, construction and maintenance of the facilities and equipment used in manufacturing, processing, packaging, testing, or storage of its drug products, *regardless of where such facilities and equipment are located*. FDA, in fact, inspects each applicant's manufacturing facilities, *whether domestic or foreign*, to ensure that the establishment is capable of manufacturing the proposed drug product in accordance with FDA requirements, and that the submitted data is accurate and complete. . . .

In sum, if Apotex wishes to sell a generic pharmaceutical product in the United States, it cannot simply "export" such product to the United States and offer it for sale. The product may only be lawfully sold if Apotex has met *all* of the statutory and regulatory requirements for FDA approval, has complied with *all* of FDA's CGMP requirements, and has passed inspection, regardless of where the facilities are located.

Counter-Mem. ¶¶ 42-43, 45 (emphasis in original).

<sup>20</sup> FDA Import Alert Letter to Apotex, Inc. (Aug. 20, 2009) (noting ongoing compliance obligations) [R110].

<sup>21</sup> 21 U.S.C. § 355(e) [R3]; 21 U.S.C. § 355(j)(6) [R3]; 21 C.F.R. § 314.150 [R40]; 21 C.F.R. § 314.151 [R41] (statute does not provide for compensation for revocation of an ANDA).

<sup>22</sup> See *Apotex Inc. v. FDA*, 508 F. Supp. 2d 78, 89 (D.D.C. 2007) (upholding FDA's revocation of approved ANDA for Apotex's generic drug omeprazole) [R115].

data and information”; “can be bought and sold like all other property”; and the applicant has “the exclusive right to possess, use and enjoy the ANDA and the products approved thereunder.”<sup>23</sup> Apotex does not cite to U.S. or international law for these conclusory assertions.<sup>24</sup> Instead, Apotex refers generally to *Black’s Law Dictionary’s* definition of “property.”<sup>25</sup> That dictionary definition in no way establishes that a tentatively-approved (or even finally-approved) application for revocable permission to export generic drugs to the United States for sale by others constitutes property for purposes of NAFTA Chapter Eleven.<sup>26</sup>

22. Apotex does not explain how the protection of its business confidential information by FDA transforms an ANDA into “property.”<sup>27</sup> Apotex may have a right under U.S. law to have its disclosures to FDA kept confidential, but that cannot transform the ANDA process into some form of investment that the NAFTA intended to protect under Article 1139(g).

23. Apotex states that “an ANDA can be bought or sold,” but it neither asserts nor establishes that its tentatively-approved ANDAs had value.<sup>28</sup> Instead, Apotex elides the issue of value by interchangeably discussing three discrete concepts: (1) finally-approved ANDAs; (2) finally-approved ANDAs plus associated products; and (3) tentatively-approved (what Apotex

---

<sup>23</sup> Counter-Mem. ¶ 37.

<sup>24</sup> The Tribunal may look to U.S. law as informative because it is the law of the host State. See Rosalyn Higgins, *The Taking of Property by the State: Recent Developments in International Law*, 176 RECUEIL DES COURS 263, 270 (1982) (for a definition of “property . . . [w]e necessarily draw on municipal law sources and on general principles of law”) [R128]; *Glamis Gold Ltd. v. United States*, NAFTA/UNCITRAL, Award ¶ 37 (June 8, 2009) [R119] (examining U.S. law to determine whether an “unpatented mining claim” constituted “property”).

<sup>25</sup> Counter-Mem. ¶ 37, n.34 (citing BLACK’S LAW DICTIONARY \*1 (9th ed. 2009) [C60]).

<sup>26</sup> BLACK’S LAW DICTIONARY \*1 (“property”) [C60].

<sup>27</sup> Counter-Mem. ¶ 37.

<sup>28</sup> *Id.* (emphasis added).

sometimes calls “unapproved”) ANDAs.<sup>29</sup> Far from establishing that its tentatively-approved ANDAs constitute valuable property, Apotex admits that “[i]f an ANDA is never approved and the product can never be sold, such ANDA is essentially worthless.”<sup>30</sup> Indeed, even the sale of an approved ANDA would not change its essential character, which is not property but permission to sell generic drugs in the United States that is revocable under law without compensation.

24. As for “exclusivity,” Apotex cannot meet even the definition on which it relies in *Black’s Law Dictionary*. That dictionary states that “private property,” one of a long list of definitions of types of property, is “Property—protected from public appropriation—over which the owner has exclusive and absolute rights.”<sup>31</sup> This definition does not describe Apotex’s interest in the ANDA, which is a tentatively-approved application for revocable permission that is subject to continual regulatory oversight and monitoring in the public interest. It can hardly be said to grant Apotex “exclusive and absolute rights.” Nor is Apotex protected from changes to, or revocation of, its ANDAs if FDA finds grounds for those actions. Moreover, the tentatively-approved ANDAs, which are the basis of Apotex’s NAFTA claims, cannot be “exclusive” or “absolute,” because no products can be sold until those applications are finally approved.

25. Finally, even if Apotex were asserting some market-based notion of exclusivity, an approved ANDA does not convey exclusivity in the market for its generic products. Any manufacturer of that generic drug can attempt to obtain similar permission, enter the same

---

<sup>29</sup> At times in its Counter-Memorial, Apotex refers explicitly to “unapproved ANDAs.” *Id.* At other times, it discusses approved ANDAs and the rights granted by that approval. *Id.* ¶¶ 38, 44. Elsewhere, Apotex refers to the “ANDA and the products approved thereunder.” *Id.* A tentatively-approved ANDA provides no permission to export generic drugs to the United States for sale.

<sup>30</sup> *Id.* ¶ 38.

<sup>31</sup> BLACK’S LAW DICTIONARY \*3 [C60].

market, and produce the same product (with the same chemical formulation), subject to any patent rights. There is, therefore, no “exclusivity” in the ANDAs for the sale of Apotex’s generic products.<sup>32</sup>

26. Apotex further argues that its tentatively-approved ANDAs are “property” because Apotex spent money preparing them.<sup>33</sup> Apotex thus argues: “Without question, the costs Apotex has incurred in meeting the specific FDA requirements for approval of its sertraline and pravastatin ANDAs are investments under Article 1139.”<sup>34</sup> This assertion is wrong, as those costs were incurred: (1) in Canada, and (2) to meet regulatory requirements to export a particular product for sale by others. As such, they cannot constitute investments under NAFTA Article 1139.

27. To support its argument, Apotex identifies various activities that are subject to the “strict requirements” of U.S. laws and regulations for which Apotex incurred costs.<sup>35</sup> These activities include “testing, manufacturing, and labeling of the ANDA products,” including “laboratory controls, stability testing programs, batch production and process controls, in-process controls for sampling, and procedures for indentifying and storing, handling, sampling, testing and approving drug products, components and containers” as well as “documentation of such testing, sampling, and manufacturing, and the controls for each.”<sup>36</sup> These costs, however, were all

---

<sup>32</sup> The only exclusivity is the 180-day exclusivity. But far from asserting that it “owns” 180-day exclusivity for either sertraline or pravastatin, Apotex merely sought to deny the benefits of exclusivity to its competitors.

<sup>33</sup> Counter-Mem. ¶ 44.

<sup>34</sup> *Id.*

<sup>35</sup> *Id.* ¶ 42 (citing 21 C.F.R. § 211 *et seq.* [C43]).

<sup>36</sup> *Id.*

incurred in *Canada*, not in the United States.<sup>37</sup> Such costs, on their face, cannot be investments in the United States sufficient to support this Tribunal's jurisdiction.<sup>38</sup>

28. Furthermore, Apotex misreads the *Grand River* and *Bayview* awards to suggest that costs incurred outside the United States in compliance with a U.S. regulatory regime can constitute investments in the United States. Apotex relies on dicta that "a salient characteristic of an investment" is "regulation by the law of a state other than the state of the investor's nationality."<sup>39</sup> The *Grand River* and *Bayview* tribunals made clear, however, that the law of the host State is one "salient," but not sufficient, factor in determining whether expenditures qualify as an "investment" under NAFTA Article 1139.<sup>40</sup> In fact, the *Bayview* tribunal declined jurisdiction over all of the claimants' claims because the claimants had not made an investment in the territory of the respondent State, stating:

In the opinion of the Tribunal, it is quite plain that NAFTA Chapter Eleven was not intended to provide substantive protections or rights of action to investors whose investments are wholly confined to their own national States, in circumstances where those investments may be affected by measures taken by another NAFTA State Party. The NAFTA should not be interpreted so as to bring about this unintended result.<sup>41</sup>

---

<sup>37</sup> See Mem. ¶ 43 (noting that Apotex concedes it manufactures its drugs entirely in Canada) & n.77 (citing Apotex's ANDAs for sertraline and pravastatin (Application to Market a New Drug, Biologic, or Antibiotic Drug for Human Use for Sertraline at 003, 4335 (Oct. 27, 2003) [R44] and Application to Market a New Drug, Biologic, or Antibiotic Drug for Human Use for Pravastatin at 003, 5370 (Dec. 21, 2001)) [R45]).

<sup>38</sup> See *Grand River* Award ¶ 89 ("The Claimants' investment in *Grand River's* cigarette plant in Canada does not satisfy the jurisdictional requirements under NAFTA Article 1101") [R76]; *Bayview* Award ¶¶ 112-113 ("That brings us to the crucial question: whether the Claimants have an investment 'in the territory of [Mexico].' In our view it is clear they do not.") [R69]; *In re Consolidated Canadian Cattle Claims*, NAFTA/UNCITRAL, Award on Jurisdiction ¶ 111 (Jan. 28, 2008) ("Because Claimants concede they are only domestic investors, their claim must fail") [R70].

<sup>39</sup> Counter-Mem. ¶ 39, n.37 (citing *Grand River* Award ¶ 88 [R76]).

<sup>40</sup> *Grand River* Award ¶ 88 (citing with approval to *Bayview* Award ¶¶ 98-99 [R69]) [R76].

<sup>41</sup> *Bayview* Award ¶ 103 [R69].

29. The *Grand River* tribunal similarly declined jurisdiction over most of the claimants' claims, concluding that it does "not have jurisdiction over claims that are based on injury to investments located in one NAFTA Party on account of actions taken by authorities in another."<sup>42</sup> The mere regulation of Apotex's foreign products (however extensive) therefore cannot transform the costs incurred in developing those products into U.S. investments.

30. Moreover, even if Apotex had incurred these regulatory costs in the United States, they would not constitute "investments" under NAFTA Article 1139. As the *Grand River* tribunal made clear, where a company must meet "regulatory requirements" to sell its products in the United States, the costs of such compliance themselves are not "investments."<sup>43</sup> Rather, as discussed below, those costs are "incident to 'commercial contracts for the sale of goods or services,' which fall outside of Article 1139's definition of investment."<sup>44</sup>

31. Thus, neither Apotex's ANDAs nor its activities in Canada nor the costs incurred there in meeting the requirements of the U.S. regulatory regime for exporting its goods are investments in the United States. Apotex has failed to carry its burden of proving that it made an "investment" under NAFTA Article 1139(g).

**B. Apotex Has Not Made "Investments" In The United States Merely Because It Purchased Goods In The United States For Export, Designated A U.S. Agent And Distributor, And Incurred Litigation Expenses In The United States**

32. Apotex alleges that three additional activities in the United States qualify as investments under Article 1139(h): (1) its purchases of inactive ingredients from U.S.-based suppliers for

---

<sup>42</sup> *Grand River Award* ¶ 87; *see also* ¶¶ 5-6 (finding that the Tribunal "does not have jurisdiction over the claims of Kenneth Hill, Jerry Montour and Grand River, because they did not have an investment in the United States," but "does have jurisdiction over Arthur Montour's claim," because "he created a substantial business in the United States, importing cigarettes manufactured by Grand River and distributing them . . . in the United States") [R76].

<sup>43</sup> *Id.* ¶ 115.

<sup>44</sup> *Id.*



export to Canada, (2) its designation of Apotex Corp. as its distributor and agent, and (3) its legal fees in pursuing the litigation related to sertraline and pravastatin.<sup>45</sup>

33. These activities do not constitute an investment under NAFTA Article 1139(h). The definition of “investment” in NAFTA Article 1139(h) includes:

(h) interests arising from the commitment of capital or other resources in the territory of a Party to economic activity in such territory, such as under

(i) contracts involving the presence of an investor’s property in the territory of the Party, including turnkey or construction contracts, or concessions, or

(ii) contracts where remuneration depends substantially on the production, revenues or profits of an enterprise[.]

34. This article must be read with NAFTA Article 1139(i), which clarifies that “investment does *not* mean”:

(i) claims to money that arise solely from

(i) commercial contracts for the sale of goods or services by a national or enterprise in the territory of a Party to an enterprise in the territory of another Party, or

(ii) the extension of credit in connection with a commercial transaction, such as trade financing, other than a loan covered by subparagraph (d); or

(j) any other claims to money,

that do not involve the kinds of interests set out in subparagraphs (a) through (h).<sup>46</sup>

None of Apotex’s alleged U.S.-based activities are investments under Article 1139(h), particularly as qualified by Article 1139(i).

---

<sup>45</sup> Counter-Mem. ¶¶ 48-62.

<sup>46</sup> Emphasis added.

35. Apotex has failed to identify what investment “interests” arose from its purchase of U.S. supplies, the designation of a U.S. agent and distributor, or its U.S. legal fees. To qualify as an investment under Article 1139(h), more than the mere commitment of funds is required—Apotex also must have a cognizable “interest” that arises from the commitment of those resources. NAFTA Article 1139(h)(i) states that such interests might arise from, for example, turnkey or construction contracts or concessions. Similar interests might arise, according to NAFTA Article 1139(h)(ii), from “contracts where remuneration depends substantially on the production, revenues or profits of an enterprise.” Apotex, however, fails to point to any interests arising from its U.S. purchases, its designation of a U.S. distributor and agent, and U.S. legal fees that are the same or similar to those listed as examples in Article 1139(h).<sup>47</sup> Apotex’s expenses merely relate to Apotex’s Canadian-based manufacturing and export operations and related ANDAs.<sup>48</sup>

36. Apotex has not alleged, let alone established, any “interests” in the United States arising from the purchase of ingredients from U.S. suppliers, the designation of a U.S. agent and distributor, or the retention of U.S. counsel. Nor has Apotex explained how any potential benefits it obtained from these transactions are the same as or similar to those listed in NAFTA Article 1139(h)(i-ii) such that they qualify as “investments” in the United States.

37. With respect to the purchase of U.S. supplies, Apotex alleges nothing more than that these purchases were undertaken to facilitate Apotex’s manufacture *in Canada* of the generic

---

<sup>47</sup> Under the principle of *ejusdem generis* (“of the same kind”), “general words following or perhaps preceding special words are limited to the genus indicated by the special words.” IAN BROWNLIE, PRINCIPLES OF PUBLIC INTERNATIONAL LAW 604 (6th ed. 2003) [R129]. In other words, to qualify as an “investment” under Article 1139(h), Apotex must demonstrate that its claimed interests are “of the same kind” as the examples used in the text of the treaty.

<sup>48</sup> Apotex’s ANDAs, for instance, require Apotex to designate an agent for service of process, because Apotex is not present in the United States. Counter-Mem. ¶ 50 (citing Apotex’s sertraline and pravastatin ANDAs).

drugs it was seeking approval to export to the United States.<sup>49</sup> Apotex's purchase of ingredients from U.S. suppliers is a "commercial contract for the sale of goods," which are generally excluded from NAFTA's definition of "investment" under 1139(i). As the *Bayview* tribunal found in applying Article 1139(i), "[t]he economic dependence of an enterprise upon supplies of goods . . . from another State is not sufficient to make the dependent enterprise an 'investor' in that other State."<sup>50</sup>

38. Apotex's engagement of U.S. attorneys and the designation of a distributor and agent similarly constitute "commercial contracts for the sale of . . . services" incident to the regulatory requirements of the U.S. market and do not involve the kinds of interests that arise from the "commitment of capital or other resources in the territory of a Party." They are thus excluded as "investments" by Article 1139(i). The *Grand River* tribunal referred to Article 1139(i) in rejecting similar activities as investments under NAFTA Chapter Eleven.<sup>51</sup> Indeed, that tribunal found expressly that the appointment of a separate company to distribute the claimants' products does not transform the distributor into an "investment" under the NAFTA.<sup>52</sup> Apotex cites no relevant authority for interpreting these provisions differently.<sup>53</sup>

---

<sup>49</sup> Counter-Mem. ¶¶ 54-55.

<sup>50</sup> *Bayview* Award ¶ 104 [R69].

<sup>51</sup> *Grand River* Award ¶¶ 115-116 (noting that escrow-payment and regulatory requirements in relation to cigarette sales "were incident to 'commercial contracts for the sale of goods or services,' which generally fall outside of Article 1139's definition of investment," and concluding that such escrow "payments have not been shown to constitute an investment within the meaning of Article 1139") [R76].

<sup>52</sup> *Grand River* Award ¶ 85 ("The other distributor—Tobaccoville—is an independent U.S. corporation that purchases Grand River's cigarettes and distributes them off reservation under the terms of a contract with Grand River. It is a U.S. owned and controlled entity. It is not, and could not be, claimed as part of the Claimants' investment.") [R76]; see also Apotex Inc. Corporate Introduction, Dec. 10-19, 2008 [R111] (Apotex Inc.'s organizational chart).

<sup>53</sup> Apotex cannot rely on the decisions in *SGS v. Philippines* and *SGS v. Pakistan* to support its argument that its activities in their totality should lead the Tribunal to consider it an investor with an investment in the territory of the United States. Counter-Mem. ¶¶ 58-59 (citing *SGS Société Générale de Surveillance SA v. Islamic Republic of Pakistan*, ICSID Case No. ARB/01/13, Decision on Objections to Jurisdiction (Aug. 6, 2003) ("*SGS v. Pakistan*

39. In short, Apotex cannot establish that it made an “investment” in the United States by drawing from a grab bag of U.S. business activities. If a foreign exporter could establish that it made an investment in the United States merely by hiring a U.S. distributor, agent, or lawyer, or by purchasing goods from a U.S. supplier, it would throw open the doors of investment treaty arbitration to anyone engaged in cross-border trade and radically expand the scope of the substantive obligations undertaken by the NAFTA Parties. Such a far-reaching scheme is not what the NAFTA Parties agreed to when they adopted Chapter Eleven.<sup>54</sup> Apotex has failed to establish that it is an investor with an investment in the United States, and thus its claims must be dismissed in their entirety.

## **II. The Regulatory And Judicial Measures Underlying Apotex’s Pravastatin Claims Fall Outside The Tribunal’s Jurisdiction**

40. Apotex’s Counter-Memorial confirms that the two measures underlying its pravastatin claim—the April 11, 2006 FDA letter decision, and the subsequent U.S. court actions—fall outside the Tribunal’s jurisdiction for two reasons. Apotex’s claims based on the FDA letter decision, which are not subject to a requirement of judicial finality, are time-barred because Apotex failed to bring them within NAFTA’s three-year limitations period. Apotex’s claims

---

Decision”) [C67]; and *SGS Société Générale de Surveillance SA v. Philippines*, ICSID Case No. ARB/02/6, Decision on Objections to Jurisdiction (Jan. 29, 2004) (“*SGS v. Philippines* Decision”) [C68]. As an initial matter, neither case involved an interpretation of the NAFTA, which provides its own definition of “investment.” In both cases, moreover, the claimant established “liaison offices” in the respondent States. *SGS v. Pakistan* Decision ¶ 137, 140 (expenditures incurred in establishing and operating a liaison office in the host State constituted an investment) [C67]; *SGS v. Philippines* Decision ¶¶ 101, 103 (expenditures incurred in establishing and operating “a substantial office, employing a significant number of people,” in the host State constituted an investment) [C68]. Apotex has not alleged any such investments in the United States, conceding that it “does not reside or have a place of business in the United States.” Counter-Mem. ¶ 50. In addition, in *SGS v. Pakistan*, the claimant had acquired a concession, which is a recognized investment under the NAFTA. NAFTA art. 1139(h)(i); *SGS v. Pakistan* Decision ¶ 135 (“Pakistan effectively granted SGS a public law concession . . . , since SGS was conferred certain powers that ordinarily would have been exercised by the Pakistani Customs service[.]”) [C67]. Apotex does not claim to have obtained, or sought to obtain, a concession.

<sup>54</sup> *In re Consolidated Canadian Cattle Claims Award* ¶¶ 127, 188 (finding “common, concordant, and consistent practice” of the three NAFTA Parties that Article 1101 is the “gateway” rendering Chapter Eleven protections available only to “investors” with “investments” in the territory of the host State as those terms are defined in NAFTA 1139) [R70].

based on U.S. court actions, which are subject to a requirement of judicial finality, are barred because Apotex failed to exhaust available judicial remedies.

41. As addressed below, Apotex concedes that the FDA letter decision was issued more than three years before Apotex brought its pravastatin claim under the NAFTA. That claim is barred by NAFTA's three-year limitations period. Although Apotex seeks to toll the limitations period by linking the FDA measure to later court actions, NAFTA Chapter Eleven tribunals have consistently rejected such efforts as contrary to the plain language of the agreement. The FDA measure thus falls outside the Tribunal's jurisdiction.

42. Apotex separately challenges U.S. courts' adjudication of its pravastatin claim, but that claim also fails. As addressed below, Apotex admits that it cannot challenge non-final judicial decisions under the NAFTA and that the judicial decisions it challenges were not final. Apotex seeks to excuse its failure by claiming it would have been "obviously futile" to seek finality in U.S. courts. In fact, Apotex had two remedies available to it. Apotex could have sought certiorari in the U.S. Supreme Court or continued litigating its claims on the merits in the district court. Instead, Apotex voluntarily chose to abandon its claims, and thus cannot challenge the non-final judicial decisions under NAFTA Chapter Eleven.

43. The time-barred FDA measure and the non-final judicial decisions underlying the pravastatin claim fall outside the Tribunal's jurisdiction.<sup>55</sup> Accordingly, the pravastatin claim should be dismissed in its entirety.

---

<sup>55</sup> Apotex's sertraline claim, by contrast, appears not to be time-barred. Apotex previously alleged that the January 3, 2005 decision of the District Court for the Southern District of New York concerning sertraline was "tantamount to a denial of justice as defined by international law and constitutes an expropriation of Apotex's investment." Notice of Intent related to sertraline claim at 5 (Sept. 21, 2007) ("Sertraline NOI"); Sertraline NOA ¶ 50. The United States observed in its Memorial on Jurisdiction that, on its face, the challenged measure is time-barred, as it

**A. Apotex's Challenge To An FDA Measure Older Than Three Years Is Barred By NAFTA's Three-Year Limitations Period**

44. In an effort to circumvent NAFTA's clear limitations period, Apotex has sought to drop its previous claim that the FDA measure is a separate breach under the NAFTA. Apotex now argues that the FDA measure is part of a continuing breach by the U.S. courts. Specifically, Apotex claims that the FDA measure and the subsequent litigation relating to that measure are "part of the same single, continuous action," with the later court proceedings tolling the earlier FDA measure.<sup>56</sup>

45. Nothing in the text or jurisprudence of NAFTA Chapter Eleven suggests that a party can evade NAFTA's limitations period in this manner. Apotex's arguments, in fact, contradict the text of NAFTA Article 1116(2), the decisions of other NAFTA Chapter Eleven tribunals, and Apotex's own pleadings in this case.

46. The text of Article 1116(2) does not support Apotex's "continuing breach" theory. That provision states:

An investor may not make a claim if more than three years have elapsed from the date on which the investor first acquired, or should have first acquired, knowledge of the alleged breach and knowledge that the investor has incurred loss or damage.

Under the plain terms of the Agreement, Apotex cannot bring a NAFTA Chapter Eleven claim challenging the April 11, 2006 FDA letter decision if more than three years have elapsed from

---

occurred more than three years before the United States received Apotex's Sertraline NOA, on December 11, 2008. Mem. ¶ 50. Apotex states in its Counter-Memorial that its sertraline claim "is based on the actions of at least three U.S. federal courts, including the New York District Court, the Federal Circuit, and the Supreme Court[.]" Counter-Mem. ¶ 68. To the extent Apotex's sertraline claim alleges breach and loss arising out of final judicial acts of U.S. courts—and not, as discussed below, on the non-final act of a U.S. district court—then that claim is not time-barred under NAFTA Article 1116(2).

<sup>56</sup> *Id.* ¶ 86.

when Apotex first acquired, or should have acquired, knowledge of the FDA measure that allegedly breached NAFTA Chapter Eleven and knowledge that it incurred loss or damage as a result of that measure.

47. Apotex does not dispute that in April 2006 it acquired knowledge of the FDA measure and knowledge of any resulting loss or damage allegedly arising from that measure.<sup>57</sup> Apotex, in fact, preemptively challenged the FDA measure in court on April 5, 2006, claiming that Apotex had been “adversely affected by final agency action and/or agency action unlawfully withheld.”<sup>58</sup>

48. Nor is there any dispute that Apotex brought its NAFTA pravastatin claim in June 2009—more than three years after Apotex first acquired knowledge of the alleged breach and loss arising from the FDA measure.<sup>59</sup> The April 2006 FDA letter decision thus is excluded from the Tribunal’s jurisdiction by the plain terms of Article 1116(2).

49. Apotex’s argument, moreover, has been considered and rejected by other NAFTA Chapter Eleven tribunals, which have held that the limitations period applicable to a discrete government measure, like the FDA’s April 11, 2006 letter decision, is not tolled by “litigation” or “court decisions” relating to that measure.<sup>60</sup> The *Mondev* tribunal, for instance, rejected a claimant’s attempt to toll the limitations period through a court action against the underlying

---

<sup>57</sup> See Pravastatin NOA ¶ 30 (“Apotex was prevented from obtaining approval and timely bringing its pravastatin tablets to market in April 2006, thus causing Apotex substantial injury[.]”); Counter-Mem. ¶ 91 (“FDA approved Teva’s ANDA on April 24, 2006,” “Teva immediately launched its respective ANDA products,” and Apotex “immediately appealed the district court’s decision[.]”); see also Complaint ¶ 3, *Apotex Inc. v. FDA*, No. Civ. A.06-0627 (D.D.C. Apr. 5, 2006) (challenging FDA letter decision) [R56].

<sup>58</sup> See Complaint ¶ 10, *Apotex Inc. v. FDA*, No. Civ. A.06-0627 (D.D.C. Apr. 5, 2006) (“Apotex has standing to maintain this action, pursuant to the [Administrative Procedure Act], as a legal entity that has suffered a legal wrong and has been adversely affected by final agency action and/or agency action unlawfully withheld.”) [R56].

<sup>59</sup> Pravastatin NOA ¶ 67 (“FDA’s April 11, 2006 administrative ruling” and the subsequent judicial actions “each constitutes a violation of at least Articles 1102, 1105, and 1110 of the NAFTA”) (emphasis added).

<sup>60</sup> Counter-Mem. ¶ 83.

measures.<sup>61</sup> At issue in that case were actions of the City of Boston and the Boston Redevelopment Agency (BRA) concerning the development of commercial real estate in Boston, as well as subsequent litigation involving those actions. The tribunal declined to consider actions of the City of Boston and the BRA, as those actions had arisen before January 1, 1994, when the NAFTA entered into force. The tribunal noted, however, that “if Mondev’s claims concerning the conduct of the City and BRA had been continuing NAFTA claims as at 1 January 1994, they would now be time-barred.”<sup>62</sup> The *Mondev* tribunal thus limited its jurisdiction to claims concerning the decisions of U.S. courts, as those claims “were commenced within three years from the *final* court decisions.”<sup>63</sup> *Mondev* thus makes clear that a NAFTA claimant cannot evade NAFTA’s limitations period by filing a court action against a discrete government measure.

50. The *Grand River* tribunal similarly dismissed claimants’ efforts to circumvent NAFTA’s limitations period. Claimants in that case had argued that the NAFTA’s limitations period applied differently depending on when each U.S. state implemented an underlying measure.<sup>64</sup> The tribunal found that claimants’ approach would “render the limitations provisions ineffective in any situation involving a series of similar and related actions by a respondent state, since a claimant would be free to base its claim on the most recent transgression, even if it had knowledge of earlier breaches and injuries.”<sup>65</sup> This Tribunal likewise should reject Apotex’s

---

<sup>61</sup> *Mondev Int’l Ltd. v. United States*, NAFTA/ICSID Case No. ARB(AF)/99/2, Award ¶ 87 (Oct. 11, 2002) [R81].

<sup>62</sup> *Id.*

<sup>63</sup> *Id.* (emphasis added).

<sup>64</sup> *Grand River Enterprises Six Nations, Ltd. v. United States*, NAFTA/UNCITRAL, Decision on Jurisdiction ¶ 81 (July 20, 2006) (Claimants “maintained that there is not one limitations period, but many”) [R75].

<sup>65</sup> *Id.* The tribunal also stated:

[T]he Tribunal’s views parallel those of the NAFTA Tribunal in *Mondev*. The claimant there also faced difficulties arising from the time limitations of Articles 1116(2) and 1117(2). The claimant sought to



attempt to toll a discrete measure based on what Apotex now claims were “similar and related actions” in court.<sup>66</sup>

51. Apotex invokes the *Loewen* tribunal’s recitation of the U.S. statement that “judicial action is a single action from beginning to end so that the State has not spoken (and therefore no liability arises) until all appeals have been exhausted.”<sup>67</sup> This statement, while correct, does not support Apotex’s theory. As Apotex itself admits, the FDA measure is an “administrative decision,” not a “judicial action,”<sup>68</sup> and the NAFTA does not require claimants to exhaust all available remedies before challenging non-judicial decisions.<sup>69</sup> *Loewen*, therefore, is irrelevant on this point.

52. Apotex’s reading also contradicts its own pleadings in this case. Apotex argued in its Pravastatin NOA that the “FDA’s April 11, 2006 administrative ruling” and the subsequent judicial actions “each constitutes a violation of at least Articles 1102, 1105, and 1110 of the NAFTA.”<sup>70</sup> Apotex now argues that the April 2006 FDA decision and the subsequent decisions

---

surmount these with the argument that it could have certain knowledge that it had incurred injury from events prior to the limitations period only after it knew the outcome of *subsequent litigation* that stood to quantify the extent of loss was known. The Tribunal did not agree, finding that “a Claimant may know that it has suffered loss or damage even if the extent of quantification of the loss or damage is still unclear.”

*Id.* ¶ 78 (quoting *Mondev Award* ¶ 87 (emphasis added) [R81]).

<sup>66</sup> See Counter-Mem. ¶ 68 (arguing that the FDA and judicial measures constitute a “single, continuous set of underlying factual bases” that “cannot be parsed into separate, unrelated events.”); see also ¶¶ 83, 85-86.

<sup>67</sup> *Id.* ¶ 84 (quoting *Loewen Group v. United States*, NAFTA/ICSID Case No. ARB(AF)/98/3, Award ¶ 143 (June 26, 2003) [R78]).

<sup>68</sup> Pravastatin NOA ¶ 62; Counter-Mem. ¶ 86.

<sup>69</sup> See *Loewen Award* ¶¶ 158-64 (discussing relationship between NAFTA’s waiver and exhaustion requirements and noting that “Article 1121 involves no waiver of the duty to pursue local remedies in its application to a breach of international law constituted by a judicial act”) [R78].

<sup>70</sup> Pravastatin NOA ¶ 67 (emphasis added).

of U.S. courts “cannot be parsed into separate, unrelated events.”<sup>71</sup> Apotex should not be permitted to blow hot and cold, advancing contradictory positions when necessary to fit its claims within the jurisdictional requirements of the NAFTA.<sup>72</sup>

53. Apotex’s effort to toll a regulatory measure by linking it to a subsequent judicial challenge of that measure should be rejected. The NAFTA does not allow a party, through the mere filing of a court case, to toll the limitations period prescribed by the treaty for challenge of a discrete regulatory measure. Were it otherwise, a party could easily circumvent NAFTA’s “clear and rigid limitation defense, which . . . is not subject to any suspension, prolongation or other qualification.”<sup>73</sup>

54. Apotex is not excused from failing to challenge the FDA measure within NAFTA’s three-year limitations period. The measure itself was taken in April 2006, litigation over the measure ended in August 2006, and Apotex voluntarily dismissed claims relating to the measure in October 2006. Apotex delayed submitting its Pravastatin NOA until June 5, 2009. Apotex had ample time to bring its NAFTA claim challenging the FDA measure, but chose not to do so. Given Apotex’s stated knowledge of alleged breach and loss in April 2006, Apotex’s claim that FDA’s April 11, 2006 letter decision breached NAFTA Articles 1102, 1105, and 1110 is time-barred by Article 1116(2) and must be dismissed.<sup>74</sup>

---

<sup>71</sup> Counter-Mem. ¶ 68.

<sup>72</sup> See BIN CHENG, GENERAL PRINCIPLES OF LAW AS APPLIED BY INTERNATIONAL COURTS AND TRIBUNALS 141-42 (1953) [R130] (“It is a principle of good faith that ‘a man shall not be allowed to blow hot and cold—to affirm at one time and to deny at another[.]’”) (quoting *Cave v. Mills*, (1862) 158 Eng. Rep. 740 (Court of Exchequer) [R120]); see also *Oil Field of Texas, Inc. v. Government of Iran*, Award, Case No. 43, 1 IRAN-U.S CL. TRIB. REP. 347, 376 (1982) (Concurring Opinion of Judge Mosk) (quoting same) [R121].

<sup>73</sup> *Grand River Decision on Jurisdiction* ¶ 29 [R75].

<sup>74</sup> Pravastatin NOA ¶ 67. Apotex has alleged that, in addition to FDA’s April 11, 2006 letter decision, the D.C. District Court, and the June 6 and August 17, 2006 decisions of the D.C. Circuit “each” constitutes a violation of

**B. Apotex Acknowledges That It Cannot Challenge Non-Final Judicial Acts, But Erroneously Claims That It Would Have Been “Obviously Futile” To Seek Finality In U.S. Courts**

55. Apotex is dissatisfied with the adjudication of its pravastatin claim by U.S. courts. Apotex disagrees with the U.S. District Court for the District of Columbia’s decision upholding FDA’s exercise of administrative discretion under the applicable statute. Apotex further disagrees with the U.S. Court of Appeals for the D.C. Circuit’s decisions upholding the district court’s ruling and declining to rehear Apotex’s motion *en banc*. Apotex contends in this arbitration that these U.S. courts administered justice so deficiently as to violate Apotex’s rights under the U.S. Constitution and to put the United States in breach of its international law obligations under the NAFTA. At the same time, Apotex claims that it would have been “obviously futile” to petition the U.S. Supreme Court to review these extremely serious (albeit spurious) challenges to the U.S. federal court system. Instead, Apotex requests that this Tribunal substitute itself for the U.S. Supreme Court and sit as a supranational appellate court to review judicial decisions of lower U.S. courts. That is not the proper role of an international tribunal established under NAFTA Chapter Eleven.<sup>75</sup>

56. Apotex’s own Counter-Memorial confirms its intentions through three admissions. First, Apotex admits that under the NAFTA it cannot challenge non-final acts of U.S. courts unless

---

Article 1102, 1105, and 1110. To the extent that Apotex alleges breach and loss on the basis of the non-final acts of the district court alone, those claims also would be time-barred.

<sup>75</sup> See *Mondev Award* ¶ 126 (“Under NAFTA, parties have the option to seek local remedies. If they do so and lose on the merits, it is not the function of NAFTA tribunals to act as courts of appeal.”) [R81]; *Azinian v. United Mexican States*, NAFTA/ICSID Case No. ARB(AF)/97/2, Award ¶ 99 (Nov. 1, 1999) (“The possibility of holding a State internationally liable for judicial decisions does not, however, entitle a claimant to seek international review of the national court decisions as though the international jurisdiction seised has plenary appellate jurisdiction. This is not true generally, and it is not true for NAFTA.”) [R122]; *Waste Management Inc. v. United Mexican States*, NAFTA/ICSID Case No. ARB(AF)/00/3, Award ¶ 129 (Apr. 30, 2004) (“Turning to the actual reasons given by the federal courts, the Tribunal would observe that it is not a further court of appeal, nor is Chapter 11 of NAFTA a novel form of *amparo* in respect of the decisions of the federal courts of NAFTA parties.”) [R123].

further judicial recourse would have been “obviously futile.”<sup>76</sup> Second, Apotex admits that the pravastatin-related court measures challenged in this arbitration were not final judicial acts.<sup>77</sup> Third, Apotex admits that, following the dismissal of its petition for rehearing *en banc*, it could have sought certiorari from the U.S. Supreme Court or proceeded with its pravastatin claim on the merits in district court.<sup>78</sup> Apotex thus confirms the *availability* of further judicial recourse, although it seeks to excuse its failure to pursue that recourse by claiming that obtaining the particular relief it sought in time was so unlikely as to be “futile.” Apotex’s excuse is insufficient and incorrect.

#### **1. Apotex’s Excuse For Failing To Exhaust Available Judicial Remedies Is Insufficient**

57. The parties agree that “an act of a domestic court that remains subject to appeal has not ripened into the type of final act that is sufficiently definite to implicate state responsibility, unless such recourse is obviously futile.”<sup>79</sup> Both parties cite the *Loewen* award, which observed that “[t]he purpose of the requirement that a decision of a lower court be challenged through the judicial process . . . is to afford the State the opportunity of redressing through its legal system the inchoate breach of international law occasioned by the lower court decision.”<sup>80</sup>

58. Apotex concedes that it did not afford U.S. courts the opportunity to redress the judicial measures underlying its pravastatin claim. Instead, Apotex claims that “due to the timing of the D.C. Circuit’s order denying its petition for rehearing *en banc*, it would have been ‘obviously

---

<sup>76</sup> Counter-Mem. ¶ 71 (noting that “a Respondent may not ‘be made responsible for the [conduct of the judicial office] when no attempt . . . has been made to obtain justice from a higher court’”) (quoting authority).

<sup>77</sup> *Id.* ¶ 94 (acknowledging failure to seek certiorari from the U.S. Supreme Court).

<sup>78</sup> *Id.* (acknowledging availability of seeking certiorari).

<sup>79</sup> See Mem. ¶ 61 and Counter-Mem. ¶ 67.

<sup>80</sup> *Loewen Award* ¶ 156 (noting that the judicial finality “requirement has application to breaches of Articles 1102 and 1110, as well as Article 1105”) [R78].

futile’ for Apotex to seek certiorari at that time or to pursue its claims on their merits in the D.C. District Court.”<sup>81</sup> In other words, Apotex alleges that the 180-day market exclusivity period awarded to another company for generic pravastatin would have run 67 days after the D.C. Circuit denied Apotex’s petition for rehearing *en banc*, and thus “Apotex no longer could have obtained any meaningful effective relief, even had it eventually succeeded on the merits.”<sup>82</sup> In effect, Apotex argues that further recourse was “moot.”<sup>83</sup>

59. Apotex misunderstands the futility exception under international law, conflating the availability of a remedy with a prediction of the likelihood of obtaining preferred relief in a particular case.<sup>84</sup> For a tribunal to excuse the finality requirement, a claimant must demonstrate that further judicial recourse was obviously futile or manifestly ineffective.<sup>85</sup> It is not enough, therefore, to allege the “absence of a reasonable prospect of success or the improbability of success, which are both less strict tests.”<sup>86</sup> Judge Aréchaga, former President of the International Court of Justice, observed that States are internationally liable only for judicial decisions of “a Court of last resort, all remedies *available* having been exhausted.”<sup>87</sup> Professor Borchard adds that a claimant is not “relieved from exhausting his local remedies by alleging . . . a pretended impossibility or uselessness of action before the local courts.”<sup>88</sup> Even if the chance of the U.S.

---

<sup>81</sup> Counter-Mem. ¶ 89.

<sup>82</sup> *Id.* ¶ 96.

<sup>83</sup> *Id.* ¶¶ 94-95.

<sup>84</sup> *See id.*

<sup>85</sup> C.F. AMERASINGHE, LOCAL REMEDIES IN INTERNATIONAL LAW 206 (2nd. ed. 2004) [R131].

<sup>86</sup> *Id.*

<sup>87</sup> Jiménez de Aréchaga, *International Law in the Past Third of a Century*, 159 RECUEIL DES COURS 281-82 (1978) (emphasis added) (quoted with approval in the *Loewen Award* ¶ 153 [R78]) [R132].

<sup>88</sup> E. BORCHARD, THE DIPLOMATIC PROTECTION OF CITIZENS ABROAD 824 (1916) [R133].

Supreme Court agreeing to hear Apotex's case was remote, the availability of a remedy was certain.

60. Where an international tribunal has found obvious futility, it has done so because there "was no justice to exhaust."<sup>89</sup> That is not the case here. Apotex simply failed to pursue remedies that it concedes were legally available. Apotex argues that because the chances of a successful outcome were "unrealistic," a petition to the U.S. Supreme Court was "objectively futile."<sup>90</sup> By so pleading, Apotex invites this Tribunal to determine whether U.S. courts could have provided Apotex the relief it sought in the timeframe consistent with Apotex's litigation strategy. This is not the role assigned to international tribunals under NAFTA Chapter Eleven. NAFTA Chapter Eleven tribunals are neither meant to, nor are they well equipped to, determine the likelihood of a successful result before a Party's highest domestic court. Apotex failed to give the U.S. judicial system the opportunity to correct the alleged breaches with respect to its pravastatin claim, and thus this Tribunal lacks jurisdiction over its claim.<sup>91</sup>

## **2. Apotex's Argument That Its Appeal Was Moot Is Incorrect**

61. Even if this Tribunal were to investigate Apotex's timing concerns, it would see that Apotex had two means of obtaining the relief it now claims was "moot."<sup>92</sup> First, under 28 U.S.C.

---

<sup>89</sup> *The Finnish Ships Arbitration Award* (Finland v. U.K.), R. INT'L ARB. AWARDS 1480, 1495, 1503-5 (May 9, 1934) (rule excusing failure to appeal where reversal was "hopeless" is "most strictly construed, and if substantial right of appeal existed, failure to prosecute an appeal operated as a bar to relief") (quoting BORCHARD 823 [R133]) [R36]; see also *Robert E. Brown Case*, (U.S. v. U.K.), R. INT'L ARB. AWARDS 120, 129 (Nov. 23, 1923) (excusing claimant's failure to exhaust because there was "no justice to exhaust" where "[a]ll three branches of the Government conspired to ruin [claimant's] enterprise") [R124].

<sup>90</sup> Counter-Mem. ¶ 94.

<sup>91</sup> Indeed, as the *Jennings* case relied upon by Apotex makes clear, "any government" cannot "be made responsible for the misconduct of an inferior judicial officer when *no attempt whatever* has been made to obtain justice from a higher court." See Counter-Mem. ¶ 71 (citing John Bassett Moore, *Jennings, Laughland & Co. v. Mexico*, Case No. 374, in 3 HISTORY & DIGEST OF THE INTERNATIONAL ARBITRATIONS TO WHICH THE UNITED STATES HAS BEEN A PARTY 3135, 3136 [C64] (emphasis added)).

<sup>92</sup> Counter-Mem. ¶¶ 94-95.

§ 1254(1),<sup>93</sup> Apotex could have sought certiorari from the U.S. Supreme Court, even after Apotex's petition for rehearing *en banc* was denied. Apotex claims that seeking certiorari on its pravastatin claim would have been "absurd," because the D.C. Circuit's decision "related solely to Apotex's request for injunctive relief, and was not a decision on the merits."<sup>94</sup> Apotex implies that the U.S. Supreme Court does not hear cases relating only to procedural matters. In fact, the U.S. Supreme Court has the power to hear cases that relate only to preliminary procedural issues<sup>95</sup> and to issue stays.<sup>96</sup> Apotex itself has sought certiorari in a matter solely relating to its request for a preliminary injunction.<sup>97</sup> Apotex also has sought certiorari,<sup>98</sup> and has been party to a case where a judgment was vacated by the U.S. Supreme Court,<sup>99</sup> on matters not involving a lower court's decision on the merits. Apotex simply failed to seek such relief here.

62. Apotex, moreover, cannot run out the litigation clock and then claim insufficient time to pursue further remedies. Apotex claims to have "promptly" sought injunctive relief from the

---

<sup>93</sup> 28 U.S.C. § 1254(1) ("Cases in the courts of appeals may be reviewed by the Supreme Court by the following methods: (1) By writ of certiorari granted upon the petition of any party to any civil or criminal case, before or after rendition of judgment or decree[.]" [R42].

<sup>94</sup> Counter-Mem. ¶ 94.

<sup>95</sup> Federal Practice & Procedure § 4036 (2011) (stating that, with regard to 28 U.S.C. § 1254(1), "[e]ven more dramatic illustration of the lack of technical restrictions is provided by contrasting certiorari to the courts of appeals with certiorari to state courts. The greatest opportunity for imposing technicalistic difficulties is presented by the statutory requirement that the case be 'in' the court of appeals, but no genuine obstacle has in fact resulted. *Beyond that starting point, there is no requirement that there be a 'final' decision; once a case has come to be in a court of appeals, the Supreme Court may grant certiorari to review interlocutory decisions or procedural rulings, and may even grant review before the court of appeals has taken any action at all.*") (Emphasis added) [R90].

<sup>96</sup> Rules 22 and 23 of the Rules of the Supreme Court provide that the Court can issue stays, for example, to maintain the status quo. Apotex failed to avail itself of this procedure. *See* U.S. Sup. Ct. R. 22, 23 (2006) [R91].

<sup>97</sup> *See, e.g.,* Petition for a Writ of Certiorari, *Apotex, Inc. v. Sebelius*, No. 10-453, 2010 WL 3905552, at 11 (Oct. 4, 2010) (seeking review of Court of Appeals for the D.C. Circuit's decision to affirm district court's denial of motions for a preliminary injunction) [R116], *cert. denied*, 131 S.Ct. 1000 (2011).

<sup>98</sup> *See, e.g.,* Petition for a Writ of Certiorari, *Apotex, Inc. v. Pfizer Inc.*, No. 05-1006, 2006 WL 304672, at 5-6 (Feb. 9, 2006) (seeking review of Court of Appeals for the Federal Circuit's decision to affirm district court's dismissal for lack of subject matter jurisdiction) [R117], *cert. denied*, 549 U.S. 970 (2006).

<sup>99</sup> *See, e.g., Colacicco v. Apotex, Inc.*, 129 S.Ct. 1578, 1578-79 (2009) (vacating and remanding decision of the Court of Appeals for the Third Circuit relating to a motion to dismiss and a motion for summary judgment) [R118].

district court on its pravastatin claim,<sup>100</sup> and to have “immediately” appealed the district court’s decision denying that relief.<sup>101</sup> Apotex fails to mention, however, that once the D.C. Circuit dissolved the administrative injunction temporarily staying FDA approval of any pravastatin ANDAs, on April 24, 2006, Apotex waited 24 days before seeking expedited consideration.<sup>102</sup> Although the D.C. Circuit rendered its decision in just under three weeks—well ahead of Apotex’s proposed schedule<sup>103</sup>—Apotex then took 44 of 45 allotted days to file a 15-page petition for rehearing *en banc*<sup>104</sup>—a motion that, in any event, was not required in order to seek review by the U.S. Supreme Court, to pursue claims on the merits in the district court, or to establish judicial finality required to bring an international claim challenging a judicial measure.<sup>105</sup> After the D.C. Circuit denied Apotex’s *en banc* petition, Apotex still had 67 days to seek certiorari before the 180-day market exclusivity expired. In other words, Apotex spent 135 of those 180 days not advancing its claim in court. When the “futility” of a remedy otherwise available is the claimant’s own fault, it is to the claimant’s own detriment.<sup>106</sup>

---

<sup>100</sup> Counter-Mem. ¶ 91.

<sup>101</sup> *Id.*

<sup>102</sup> Motion of Plaintiff-Appellant Apotex, Inc. to Expedite Consideration of this Appeal, *Apotex, Inc. v. FDA*, No. 06-5105 (D.C. Cir. May 18, 2006) [R65].

<sup>103</sup> *Id.* at 1.

<sup>104</sup> D.C. Cir. R. 35(a) (2006) (“In all cases in which the United States or an agency or officer thereof is a party, the time within which any party may seek panel rehearing or rehearing *en banc* is 45 days after entry of judgment or other form of decision.”) [R92].

<sup>105</sup> See 28 U.S.C. § 1254(1) [R42], and Petition for Rehearing *en banc* of Plaintiff-Appellant Apotex Inc., *Apotex, Inc. v. FDA*, No. 06-5105 (D.C. Cir. July 21, 2006) (after D.C. Circuit issued decision on June 6, 2006, Apotex submitted its petition on July 20, 2006—44 days later) [R14].

<sup>106</sup> See *Ambatielos Case* (Greece v. U.K.), 12 R. INT’L ARB. AWARDS 83, 122 (Mar. 6, 1956)) (“It would be wrong to hold that a party who, by failing to exhaust his opportunities in the Court of first instance, has caused an appeal to become futile should be allowed to rely on this fact in order to rid himself of the rule of exhaustion of local remedies.”) [R125].



63. Second, even if Apotex decided that Supreme Court review was unlikely to provide the relief it sought, it still could have had its case heard on the merits in the D.C. District Court.<sup>107</sup> Apotex argues that pursuing substantive relief on remand would have been “absurd,” because Apotex “would have been forced to proceed at standard litigation pace, as expedited relief was no longer an option.”<sup>108</sup> This is plainly false. Just as Apotex had sought expedited consideration of its appeal before the D.C. Circuit,<sup>109</sup> it could have sought expedited consideration of its claim on the merits before the D.C. District Court.<sup>110</sup> Again, Apotex simply failed to do so.

64. Instead, after the D.C. Circuit rejected Apotex’s petition for rehearing *en banc* on August 17, 2006, Apotex waited 47 days, until October 3, 2006, to voluntarily dismiss all of its claims against FDA.<sup>111</sup> Apotex dismissed all claims “with prejudice” for 10, 20, and 40 mg strengths,<sup>112</sup> but “without prejudice” for the 80 mg strength.<sup>113</sup> The 180-day exclusivity for 80 mg generic pravastatin had not yet begun to run because the company that had been awarded 180-day exclusivity for 80 mg generic pravastatin had not yet launched that strength.<sup>114</sup> (It did not do so

---

<sup>107</sup> Counter-Mem. ¶ 95-96.

<sup>108</sup> *Id.* ¶ 95.

<sup>109</sup> See *supra* note 102 (noting Apotex’s motion for expedited consideration before the D.C. Circuit).

<sup>110</sup> See 28 U.S.C. § 1657(a) (“Notwithstanding any other provision of law, each court of the United States shall determine the order in which civil actions are heard and determined, except that the court shall expedite the consideration of any action brought under chapter 153 or section 1826 of this title, any action for temporary or preliminary injunctive relief, or any other action if good cause therefor is shown. For purposes of this subsection, ‘good cause’ is shown if a right under the Constitution of the United States or a Federal Statute . . . would be maintained in a factual context that indicates that a request for expedited consideration has merit.”) [R93]. Under the Local Civil Rules of the D.C. District Court, Rule 16.1(a) permits the judge assigned to the case to determine the schedule accordingly. See D.D.C. Local Rule 16(a) [R94].

<sup>111</sup> Stipulation of Dismissal at 2, *Apotex Inc. v. FDA*, No. Civ. A.06-0627 (D.D.C. Oct. 3, 2006) [R12].

<sup>112</sup> *Id.*

<sup>113</sup> *Id.*

<sup>114</sup> Apotex’s petition for rehearing *en banc* makes clear that “the public ha[d] no access to a generic 80mg pravastatin product” at that time. See Petition for Rehearing *en banc* of Plaintiff-Appellant Apotex Inc. at 15, *Apotex Inc. v. FDA*, No. 06-5105 (D.C. Cir. July 21, 2006); see also at 1 (stating that “[t]his appeal is of exceptional importance, not only to Appellant-Plaintiff Apotex Inc., but to the entire generic pharmaceutical industry. The panel decision refused to set aside FDA’s unreasonable and unlawful statutory interpretation of a key generic drug

until June 25, 2007.)<sup>115</sup> Notably, although Apotex preserved its ability to return to the district court to continue litigating with respect to 80 mg pravastatin, it never did.<sup>116</sup>

65. Apotex fails to mention this fact in its Counter-Memorial.<sup>117</sup> That 180-day exclusivity related to the 80 mg strength had not yet begun to run demonstrates, at a minimum, that effective relief was available to Apotex even after its petition for rehearing *en banc* was denied.<sup>118</sup> Apotex had ample time to seek relief in the D.C. District Court, or from the U.S. Supreme Court, but Apotex chose not to do so.

66. Finally, Apotex is not helped by the *Loewen* tribunal's statement that "[i]f a State attaches conditions to a right of appeal which render exercise of the right impractical, the exercise of the right is neither available nor effective nor adequate," because there were no conditions attached to Apotex's appeal.<sup>119</sup> In *Loewen*, the "condition" at issue was the requirement that claimant post a multimillion dollar *supersedeas* bond to stay execution of a jury

---

approval provision. If the Agency's administrative ruling remains in place, introduction of affordable generics will be delayed, in direct contravention of Congress' intent when enacting the controlling statutory scheme.") [R14].

<sup>115</sup> News Release, "Ranbaxy Launches Pravastatin Sodium 80 Mg Tablets" (June 25, 2007) [R112].

<sup>116</sup> Complaint at 2, *Apotex Inc. v. FDA*, No. Civ. A.06-0627 (D.D.C. Apr. 5, 2006) (requesting "immediate declaratory and injunctive relief . . . directing FDA to finally approve Apotex's ANDA No. 76-341 for pravastatin tablets on April 20, 2006") [R56].

<sup>117</sup> See Counter-Mem. ¶¶ 88-96. Apotex states that its "Pravastatin ANDA was approved by FDA on October 23, 2006." *Id.* ¶ 93. This statement, however, is misleading, as Apotex did not receive final approval of its pravastatin ANDA with respect to the 80mg strength at that time. See FDA Final Approval for Pravastatin Sodium Tablets (10, 20, and 40 mgs) and Tentative Approval for Pravastatin Sodium Tablets (80 mg) (Oct. 23, 2006) ("However, at this time we remain unable to approve your Pravastatin Sodium tablets, 80 mg because of the exclusivity issue discussed below. Thus, your Pravastatin Sodium tablets, 80 mg, remain tentatively approved and will not be eligible for final approval until the 180-day generic drug exclusivity issue noted below has been satisfactorily resolved.") [R100].

<sup>118</sup> See F.S. DUNN, THE PROTECTION OF NATIONALS 159 (1932) ("[W]here a state has a normally functioning judicial system, which offers the possibility of a remedy in a particular case, the injured foreigner must resort to such a remedy[.]") [R134].

<sup>119</sup> Counter-Mem. ¶ 96, n.115 (quoting *Loewen Award* ¶ 170 [R78]).

award.<sup>120</sup> Here, the only requirement for an appeal was a \$300 filing fee to submit its petition for certiorari.<sup>121</sup>

67. The Tribunal should not excuse Apotex's failure to obtain the requisite judicial finality simply because Apotex did not think it could obtain its preferred relief in a timeframe consistent with its litigation strategy. The question of whether Apotex had a real chance of success in prosecuting its pravastatin claim under U.S. law should have been put to U.S. courts, and not to an international tribunal.<sup>122</sup> The Tribunal, therefore, should dismiss in their entirety Apotex's claims that the non-final judicial acts of the D.C. District Court and the D.C. Circuit breached Articles 1102, 1105, and 1110 of the NAFTA.

---

<sup>120</sup> *Loewen Award* ¶¶ 173, 208 [R78].

<sup>121</sup> See 28 U.S.C. § 1911 [R95] and Rule 38 of the Rules of the U.S. Supreme Court, U.S. Sup. Ct. R. 38 (2006) [R91].

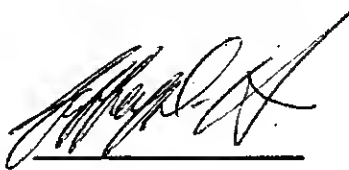
<sup>122</sup> See *Panevezys-Saldutiskis Railway Case (Estonia v. Lithuania)*, 1939 P.C.I.J. 19 (ser. A/B) No. 76 (Feb. 28) (deferring to domestic court on whether potential remedy under domestic law was available) [R126]; see also *Norwegian Loans (France v. Norway)*, 1957 I.C.J. 9, 39 (July 6) (Separate Opinion of Judge Lauterpacht) (“[H]owever contingent and theoretical these remedies may be, an attempt ought to have been made to exhaust them.”) [R127]. Commenting on Judge Lauterpacht's consideration of effectiveness in the *Norwegian Loans* case, Sir Gerald Fitzmaurice stated that “what there must be a reasonable possibility of is the existence of a possibly effective remedy and . . . the mere fact that there is no reasonable possibility of the claimant obtaining that remedy, because his case is legally unmeritorious, does not constitute the type of absence of reasonable possibility which will displace” the requirement to exhaust remedies. Gerald Fitzmaurice, *Hersch Lauterpacht—The Scholar as Judge*, 37 BRIT. Y.B. INT'L L., 1, 60-61 (1961) [R135].

**RELIEF SOUGHT**

68. For the foregoing reasons, and those stated in the United States' Memorial on Objections to Jurisdiction, the United States respectfully requests that this Tribunal dismiss all claims in their entirety with prejudice and order that Apotex bear the costs of this arbitration, including the United States' costs for legal representation and assistance.

Dated: October 17, 2011

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Jeffrey D. Kovar', is written over a horizontal line.

Jeffrey D. Kovar

*Assistant Legal Adviser*

Lisa J. Grosh

*Deputy Assistant Legal Adviser*

Jeremy K. Sharpe

*Chief, Investment Arbitration*

Neale H. Bergman

David M. Bigge

Alicia L. Cate

Patrick W. Pearsall

*Attorney-Advisers*

*Office of International Claims and Investment Disputes*

UNITED STATES DEPARTMENT OF STATE

Washington, D.C. 20520